

REMARKS

The objection is noted to the terminal disclaimer previously filed in the subject application. Applicant is filing herewith in response to prior double patenting rejections proper terminal disclaimers, signed by the undersigned attorney who has power of attorney in this application as a result of the continuation status of this application from a prior application in which the appointment of attorney power was acknowledged.

Specifically, Applicant is also submitting herewith a copy of a Petition previously filed for establishing the priority benefit herein from prior applications. It is submitted that this application is entitled to the priority benefit of prior related applications, and that the undersigned has power of attorney herein with which to properly execute the terminal disclaimers filed herewith.

Claims 7 and 9 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of application Ser. No. 10/731,068 in view of Redtenbacher '847. This rejection is respectfully traversed.

It is submitted that the application Ser. No. 10/731,068 is unavailable as a primary or principal prior-art reference since it has not yet issued as a patent, and that the secondary reference of Redtenbacher '847 alone offers no disclosure or

suggestion of the particular aspects of the claimed invention. Specifically, claims 7 and 9 variously recite the distinguishable step of “advancing an end portion of the blood-conveying conduit through the lumen of the instrument to the selected location adjacent the aorta”.

This aspect of the claimed invention is not disclosed or even suggested by Redtenbacher '847 which discloses an anastomosis stapler and anvil that are advanced within or through an intestine toward the site of ends to be joined. There is thus no suggestion in the cited reference of Applicant's claimed invention as defined in claims 7, 9 which are therefore submitted to be patentable over the cited art.

A terminal disclaimer may be filed in the future in the event the cited copending application issues with a claim or claims requiring terminal disclaimer in this application.

Claims 7-9 have been rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 2-6 of U.S. Patent No. 6,401,721.

Applicant is submitting herewith a terminal disclaimer referencing U.S. Patent No. 6,401,721 to overcome this basis for rejection. It is therefore respectfully submitted that claims 7-9 are now patentable to Applicant.

Claims 1-5 have been rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 5,749,375.

Applicant is submitting herewith a terminal disclaimer referencing U.S. Patent No. 5,749,375 to overcome this basis for rejection. It is therefore respectfully submitted that claims 1-5 are now patentable to Applicant.

Claims 11, 12 and 14 have been rejected under the judicially-created doctrine of obviousness-type double patenting over the claims 11, 12 and 15 of U.S. Patent No. 5,571,167.

Applicant is submitting herewith a terminal disclaimer referencing U.S. Patent No. 5,571,167 to overcome this basis for rejection. It is therefore respectfully submitted that claims 11, 12 and 14 are now patentable to Applicant.

The objection is noted to the amendment of the specification on August 26, 2004 regarding the priority benefit accorded this application from prior applications.

Applicant is submitting herewith a copy of the Petition referenced in the above Remarks to perfect the priority benefit in this application from prior related applications. It is submitted that the prior amendment to the specification at page 1 under Related Cases duly cites those related cases. By these documents, upon grant of the Petition, it is submitted that the effective filing date for claimed subject

in the present application derives from the earliest of the related applications, prior to July 11, 2001.

Claims 1-14 have been rejected under 35 USC §102(b) as being anticipated by Maginot '712. This rejection is respectfully traversed.

By the aforementioned Petition, this reference as a patent grant from a prior one of the related applications is removed as a reference, and these claims are therefore submitted to be patentable to Applicants.

Claim 7 has been rejected under 35 USC §102(b) as being anticipated by Barone et al. '443. This rejection is respectfully traversed with respect to this claim as amended herein.

This claim has been amended merely to define the invention with greater particularity and, as amended, now specifically recites "extravascularly positioning an end of an instrument having a lumen therethrough near a selected location along the aorta".

This aspect of the claimed invention is not disclosed in Barone et al. '443 which discloses intraluminal delivery and positioning of a tubular graft that forms an inner liner of an aortic aneurysm. There is therefore no anastomosis formed at a site on the aorta with a blood-conveying conduit that is positioned at the site extraluminally, in a manner resembling the claimed method. It is therefore respectfully submitted claim 7 is patentably distinguishable over the cited art.

Claims 1-5 have been rejected under 35 USC §103(a) as being unpatentable over the Brewster article in view of Ablaza '909. This rejection is respectfully traversed.

These claims variously recite “forming an anastomosis between the blood-conveying conduit and the blood vessel at the selected location to provide blood flow in the blood-conveying conduit outside the blood vessel”, or “anastomosing the end portion of the blood-conveying conduit and the aorta at the selected location to provide blood flow in the blood-conveying conduit outside of the aorta”.

The claimed invention thus establishes blood flow outside the aorta or other blood vessel, in contrast to merely installing a graft insert within such vessel as disclosed in the cited references. Specifically, the Brewster article is understood to disclose replacement of the aortic bifurcation, and the figures 55-6D and 55-7 referred to by the Examiner are not understood to disclose an entry below the inguinal ligament for positioning a conduit up toward an arteriotomy. At best, this reference illustrates parallel lines to show lateral cuts across the femoral arteries rather than to show the inguinal ligament, and does not illustrate or describe positioning an end of the conduit near an arteriotomy on the aorta from an entry located below the inguinal ligament.

Nor does Ablaza '909 disclose such positioning of a conduit via an entry below the inguinal ligament, as claimed. At best, this reference merely discloses installing a graft insert near the upper portion of the aorta above the heart, and offers no suggestion or motivation for extravascularly positioning such graft insert via an entry below the inguinal ligament. Thus, merely combining the deficient discloses of these references as proposed by the Examiner fails to establish a *prima facie* basis including Applicant's specifically-recited method steps from which a proper determination of obviousness can be made. It is therefore respectfully submitted that claims 1-5 are now patentably distinguishable over the cited art.

Claims 6 and 8 have been rejected under 35 USC §103(a) as being unpatentable over Kaster 4,366,819 in view of Loiterman '165. This rejection is respectfully traversed.

These claims recite "extravascularly creating an arteriotomy in the blood vessel at a selected location", and "positioning a visualization device adjacent the selected location while creating said arteriotomy and forming said anastomosis", or "extravascularly positioning an end of an instrument having a lumen therethrough near a selected location along the aorta", and "advancing an end portion of the blood-conveying conduit through the lumen to the selected location".

These aspects of the claimed invention are not disclosed or suggested by the cited references considered either alone or in the combination proposed by the

Examiner. As the Examiner correctly notes Kaster '819 fails to disclose use of a visualization device or endoscope. This deficiency of disclosure is not supplemented or 'cured' by Loiterman '165 which discloses a steerable intravascular instrument and generally references at the segment cited by the Examiner catheters and endoscopes for introducing surgical tools and materials into the vascular system. However there is no disclosure or suggestion in these combined references of the specific method steps as claimed by Applicant. It is therefore respectfully submitted that claims 6 and 8 are patentably distinguishable over the cited art.

Claim 10 has been rejected under 35 USC §103(a) as being unpatentable over Kaster 4,366,819 in view of Ruppert '913. This rejection is respectfully traversed with respect to this claim as amended herein.

This claim as amended specifically recites "extravascularly positioning near a selected location along the blood vessel a distal end of an instrument having a lumen extending therethrough between distal and proximal ends thereof", and "manipulating a surgical device extending through the lumen in the instrument to create an arteriotomy in the blood vessel at the selected location". These aspects of the claimed invention facilitate operating at a selected site through the lumen of an instrument that is introduced from a remote entry site. These aspects of the

claimed invention are not disclosed or even suggested by the cited references considered either alone or in the combination proposed by the Examiner.

Contrary to the Examiner's analysis of Kaster '819, neither the cited passage nor elsewhere in this reference is there disclosed an instrument having a lumen therethrough through which an arteriotomy is formed. The hole punch referenced by the Examiner cannot be the instrument having a lumen therethrough through which the (hole punch?) creates an arteriotomy. As the Examiner correctly notes, Kaster '819 fails to disclose the features of the hole punch.

This deficiency of disclosure is not supplemented or 'cured' by the hole punch of Ruppert '913 that may be suitable for forming an arteriotomy, but that does not have a lumen extending therethrough through which a surgical device (the same hole punch?) is manipulated to create the arteriotomy in a manner as claimed by Applicant. Thus, merely combining these references fails to establish even a *prima facie* basis including all of the claimed steps from which a proper determination of obviousness can be formed. It is therefore respectfully submitted that claim 10 as amended is now patentably distinguishable over the cited art.

Regarding the Examiner's Responses to Applicant's Arguments, it must be noted that the Brewster article in view of Ablaza '909 fails to disclose an initial entry below the inguinal ligament for "positioning an inflow end of the blood-conveying conduit..." via such initial entry, as claimed by Applicant. Also, the

transverse or lateral sets of parallel lines shown in the figures of the Brewster article are sites for transections of the vessels involved, not illustrations of inguinal ligaments. Thus, this article in view of Ablaza '909 certainly fails to suggest such initial entry as claimed since Ablaza '909 positions a graft implant in the aorta above the heart with no hint of so positioning the graft extravascularly from an entry location below the inguinal ligament.

Support for the amendments submitted herein to claim 5, 7 and 10 is disclosed, for example, in the illustrations of Figures 6-8, 11A, 12-19A and the associated written descriptions.

Applicants lists all copending applications that may be considered to contain subject matter similar or related to the present claims as including application Ser. Nos. 10/731,068; 09/903,831, and 10/824,043. It is believed that the claims of such applications are now stored in image format on the IFW system for convenient access by the Examiner. In the event such claims are not currently available, Applicant shall provide copies, upon the Examiner's request, by procedure that avoids incorporation of such claims into the prosecution history of the present application.

Reconsideration and allowance of all pending claims are solicited. The Examiner is invited to contact the undersigned attorney for the Applicant regarding any remaining issues that may expedite favorable disposition of this application.

Respectfully submitted,
THOMAS J. MAGINOT

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ATTACHMENTS:

(Copy) Petition Under 37 CFR §1.78
Terminal Disclaimer
Terminal Disclaimer
Terminal Disclaimer



COPY ✓

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

APPLICANT: Thomas J. Maginot
APPLICATION NO.: 10/726,803
FILING DATE: December 2, 2003
TITLE: Bypass Grafting Method
EXAMINER: Paul B. Prebilic
GROUP ART UNIT: 3738
ATTY. DKT. NO.: 22220-08626

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below:

Dated: 6/21/05

By: *A. C. Smith*
Albert C. Smith, Reg. No.: 20,355

MAIL STOP PETITION
COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

PETITION UNDER 37 CFR §1.78 TO CLAIM BENEFIT UNDER
35 U.S.C. §120 OF PRIOR APPLICATION

Sir:

Applicant hereby petitions in accordance with the provisions of 37 CFR §1.78(a)(3) to claim the benefit for this application under 35 U.S.C. §120 of the prior copending non-provisional application Ser. No. 09/903,831 filed on July 11, 2001 which duly claims the benefit of application Ser. No. 09/475,789 filed on December 30, 1999.

Applicant states that the entire delay between the date the claim for the benefit of the earlier application was due under 37 C.F.R. §1.78(a)(2)(ii) and the date this claim is filed was unintentional.

A check in payment of the surcharge set forth under 37 C.F.R. §1.17(t) is enclosed herewith. The Commissioner is hereby authorized to charge any required additional fee or credit any overpayment regarding this Petition to Deposit Account 19-2555. A duplicate copy of this authorization is enclosed.

Respectfully submitted,
THOMAS J. MAGINOT

Dated: 6/21/05

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